United States Patent [19]

McGrath

[11] 3,896,794

[45] July 29, 1975

[54] **VENOUS FLOW STIMULATOR**

[75] Inventor: **John Alan McGrath,** Harlow, England

[73] Assignee: **The British Oxygen Company Limited,** London, England

[22] Filed: **Dec. 14, 1973**

[21] Appl. No.: **424,813**

[52] **U.S. Cl.** .... **128/24 R**

[51] **Int. Cl.** **A61h 1/00**

[58] **Field of Search** .... 128/24 R, 64, DIG. 10, 128/DIG. 20, 325–327

[56] **References Cited**

UNITED STATES PATENTS

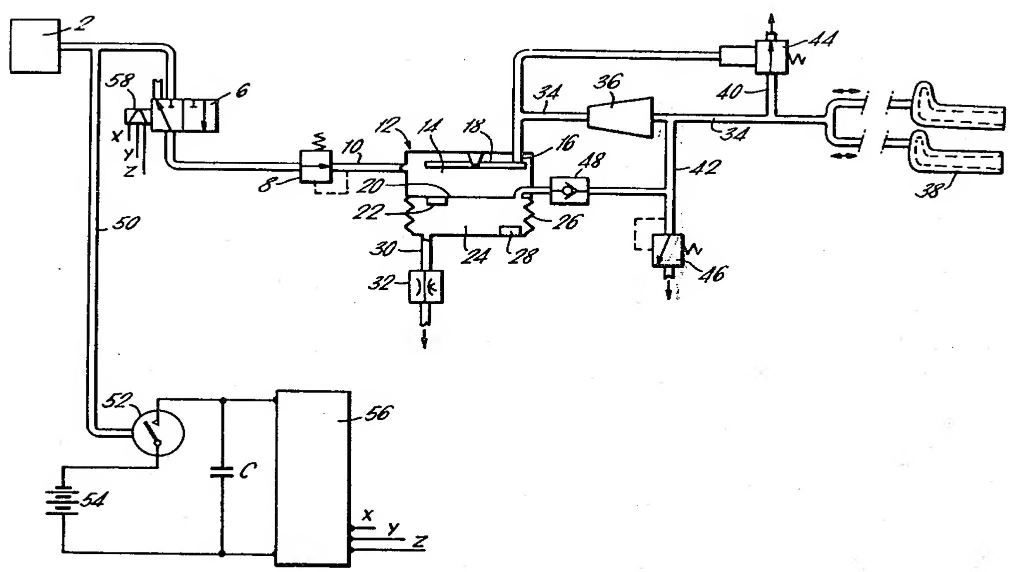
2,071,215	2/1937	Petersen	128/24 R
2,140,898	12/1938	Collens et al.	128/24 R
3,179,106	4/1965	Meredith	128/64 X
3,303,841	2/1967	Dennis	128/24 R
3,390,674	7/1968	Jones	128/DIG. 10
3,527,207	9/1970	Gottfried	128/24 R

Primary Examiner—Lawrence W. Trapp
Attorney, Agent, or Firm—Dennison, Dennison, Townshend & Meserole

[57] **ABSTRACT**

Apparatus for automatically inflating and deflating, in a predetermined pressure cycle, at least one double-walled pneumatic boot fitted to the lower limb of a patient undergoing surgery.

12 Claims, 4 Drawing Figures



PATENTED JUL 29 1975 3,896,794

SHEET 1

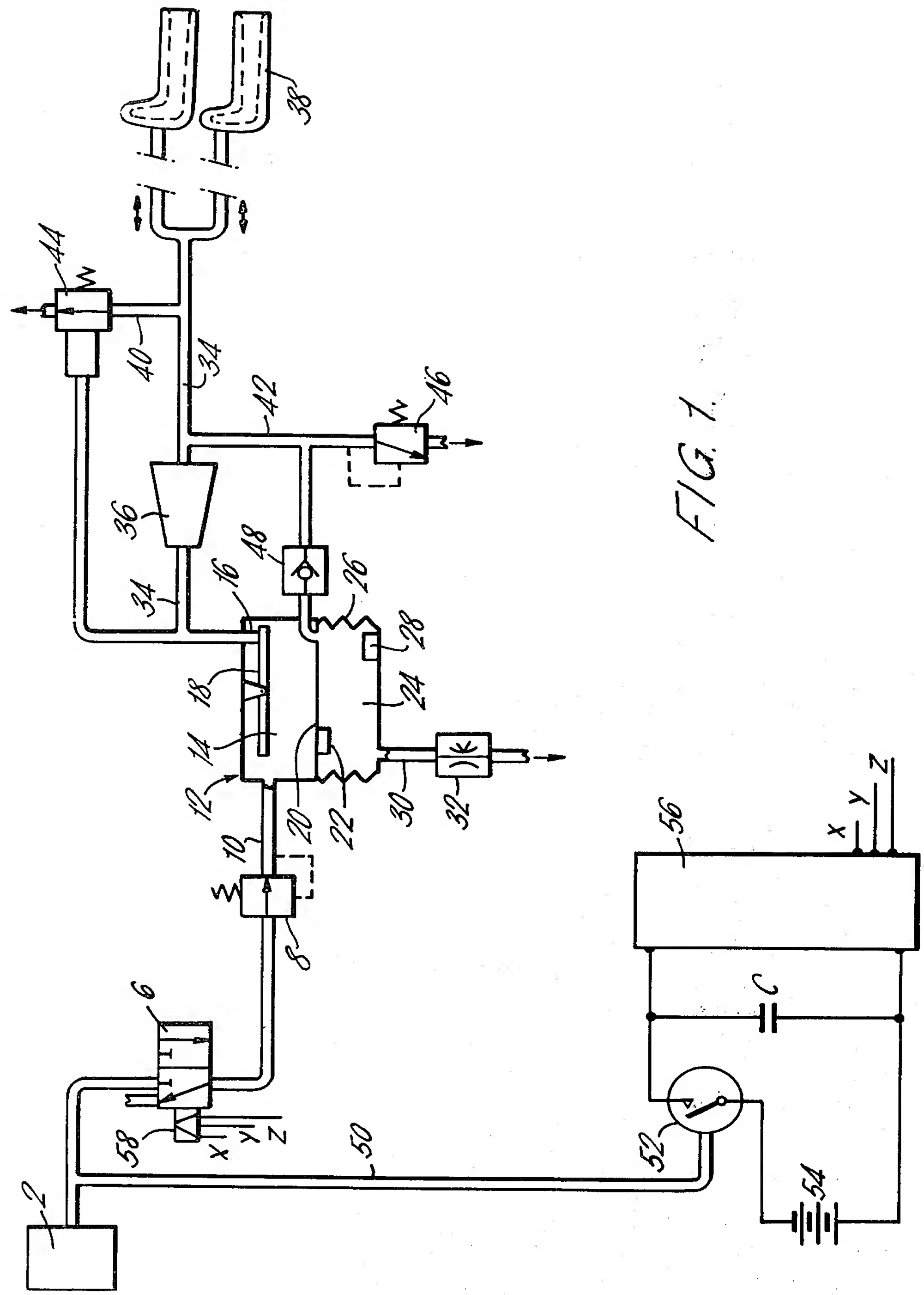


FIG. 1.

FIG. 2.

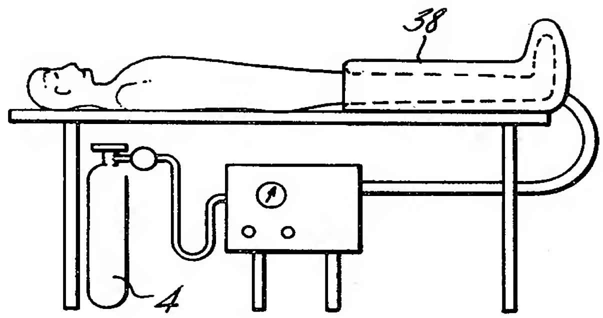


FIG. 3.

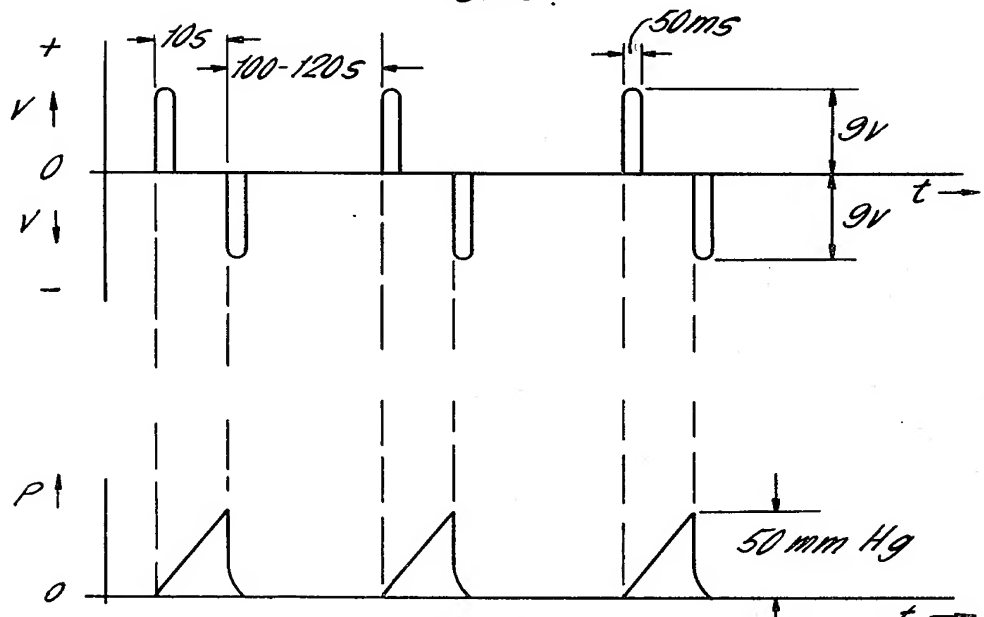


FIG. 4.

VENOUS FLOW STIMULATOR

This application relates to a venous flow stimulator, by which is meant a device used in some surgical operations to apply pulsating pneumatic pressure to the legs of a patient while undergoing surgery, in order to prevent the occurrence of post-operative deep venous thrombosis.

A known venous flow stimulator includes an electrically driven pump connected to one or a pair of inflatable pressure applicators (or pneumatic boots) adapted to be positioned around the patient's legs and feet. Pressure is applied (and released periodically) to the calf muscles of the legs of the patient by means of the boots so as to prevent stasis of blood flow in the deep veins of the legs. This reduces the risk of deep venous thrombosis occurring.

It is necessary to use the known form of venous flow stimulator to treat a patient throughout the preoperative, operative and postoperative period, treatment ceasing when the patient is ready to get out of bed. Each patient requires a machine for a relatively long period, and post-operatively the treatment may cause him discomfort and apprehension. Because the treatment is prolonged a considerable number of machines have to be employed and surgeons are reluctant to bring them into general use.

It is the aim of the present invention to provide an improved venous flow stimulator giving more effective treatment to enable the period of treatment to be reduced to that taken up by the surgical operation itself, so that the venous flow stimulator can therefore be essentially an apparatus for use only in the operating theatre.

According to the present invention there is provided a venous flow stimulator which is as claimed in the appended claims.

The venous flow stimulator of the present invention will now be described by way of example with reference to the accompanying drawings, in which:

FIG. 1 is a schema of one form of flow stimulator of the present invention;

FIG. 2 is a diagrammatic view of the stimulator in position during a surgical operation;

FIG. 3 is a graph of voltage v. time for the electrical pulses controlling operation of the stimulator, and

FIG. 4 is a graph of pressure v. time for the pneumatic pulses supplied by the stimulator to the boots encasing the patient's legs.

The venous flow stimulator shown in FIG. 1 includes a source **2** of pressurised gas usually in the form of the portable cylinder **4** shown in FIG. 2 leading through a solenoid-operated valve **6** to a flow regulator **8** (for example, of the type described in our UK patent specification No. **1,039,528**). The flow regulator **8** leads through conduit **10**, to a device **12** adapted to generate pulses of pressurised gas.

The device **12** has a gas supply chamber **14** of which an outlet **16** is controlled by a rocker valve **18**. One wall of chamber **14** is formed by a diaphragm **20** carrying a permanent magnet **22**. The device **12** also has a control chamber **24** formed by bellows **26**, of which the end wall carries a second permanent magnet **28** and a conduit **30** leading to an adjustable bleed valve **32**. Extending from the device **12** is a conduit **34** in which is positioned an injector **36**. The injector is adapted to receive gas under high pressure from conduit **34** and dilute it substantially with air from the atmosphere in order to produce larger volumes of gas at lower pressure suitable for pressurising both boots **38** fitted to the feet and legs of the patient.

Downstream of the injector **36** the conduit **34** leads to two further conduits **40** and **42**. The conduit **40** leads to the inlet of a pneumatically operated exhaust valve **44**, while the conduit **42** leads to a pressure-relief valve **46** and to the interior of chamber **24** through a non-return valve **48**.

Operation of the device **12** is governed by the pivotal position of rocker **18**, which is in turn controlled by the relative positions of magents **22** and **28**. The rocker **18** is of a soft magnetic material, such as Swedish iron, so that the rocker is able to be pivoted about its fulcrum when one or other of the magnets becomes dominant. As magnet **22** is positioned on the stationary diaphragm **20**, the force it applies on rocket **18** in the valve-closing direction is substantially constant. Because the magnet **28** is positioned on the movable end wall of bellows **26**, the magnet **28** is movable between two limit positions, in one of which its magnetic field overcomes that exerted on rocker **18** by magnet **22** and forces the rocker to pivot in the valve-opening direction. In the other limit position the magnetic field produced by magnet **28** falls below that exerted on rocket **18** by magnet **22** thus causing the rocker to be moved in the valve-closing direction.

A conduit **50** is pressurised from source **2** and leads to a pressure switch **52** which, when closed, causes a battery **54** to be connected across a capacitor C and across the input terminals of an electronic timer **56** having three outlets (labelled X, Y and Z) which are connected to respective terminals on a solenoid **58** controlling operation of valve **6**.

The detailed circuitry of timer **56** is not described in this specification, but it is based on the use of digital integrated circuitry of the COS/MOS type. In particular, although this is not shown in the drawings or described herein in any greater detail, the timer includes a square-wave oscillator adapted to be energised by battery **54**. The output of the oscillator is fed through a pulse-shaping circuit to a solid state switching circuit. Both the oscillator and pulse-shaper consist of two input, quadded NOR gates, which are available commercially, one form thereof being sold by RCA as an item in their COS/MOS CD4000A series of integrated circuits. The various components of these integrated circuits are interconnected through suitably rated electrical components to derive an output having the characteristics shown in FIG. 3 of the accompanying drawings. In a typical output, there is a positive-going pulse of 9 V amplitude and lasting **50** ms, followed after an interval of about **10** *s* by a negative-going pulse of the same amplitude and duration. At a period of between **100–120***s* after the occurrence of the negative-going pulse, a further pair of successive positive-going and negative-going pulses is generated. The positive-going pulses are labelled 'set' pulses while the negative-going pulses are labelled ' reset' pulses.

The reason for choosing set and reset pulses of opposite polarity is to avoid ambiguity in question of solenoid **58** when the circuit is first energised. If the circuit were previously deenergized while in the resting state, and if the first pulse received when next energized is a negative-going pulse, the solenoid **58** is not operated, and so the circuit is kept static until arrival of the next

positive pulse. Thus the risk is avoided of having the boots inflated during the long resting phase, and kept deflated during the intended inflation phase, as could happen were both the set and reset pulses were of the same polarity.

As already mentioned, these pulses are applied to the respective terminals of solenoid **58**, the setting pulses serving to switch the valve **6** into the position in which the source **2** applies a continuous stream of gas under pressure to device **12** through pressure regulator **8**. When a reset pulse is received, the valve is returned to the illustrated position in which no further pressurised gas is supplied to regulator **8**, the conduit upstream thereof being vented to atmosphere.

The function of capacitor C is to act as an energy-storing device to ensure that the current drain on battery **54** is reduced to the minimum constant with reliable operation, while at the same time lengthening the life of battery **54** so that it needs to be replaced only at infrequent intervals. The timing circuit **56** is such that when a set or reset pulse is applied by it to solenoid **58**, most of the energy for the pulse is derived from capacitor C. Thus ensures that the capacitor C is charged by battery **54** when no pulses are being produced by the timer, thus converting a substantially constant current drain on battery **54** into intermittent current pulses of relatively high amplitude. The function of pressure switch **52** is to disconnect the battery **54**, and disable the timer circuit, when there is insufficient gas pressure in the inlet to the pneumatic circuit to operate the pneumatic boots **38**.

The boots **38** themselves are already known, and so will not be described in great detail in this specification. The boots are double-walled, and at least the inner wall is made of a flexible plastics material which is able to take up the contours of the patient's lower leg and foot. Air under pressure is introduced into the space between the two walls. When the air of other gas is first introduced, it causes the outer wall to distend until it reaches its final shape, after which the further increase in pressure forces the inner wall more and more firmly against the patient's limb. This pressure is transmitted to the patient's veins and other blood vessels, causing them to dilate.

This contraction expels blood from the vessels in the direction dictated by the usual valving arrangements forming part of the body's vascular system. When a desired maximum pressure has been reached the pneumatic pressure in the boot is released, as by venting to atmosphere the space between the two walls of the boot. This reduction in pressure allows fresh blood to be pumped by the heart into the limbs and blood vessels. The cyclic compression and expansion applied by the boots simulates the 'massaging' of the legs' blood vessels which is normally applied by the calf muscles when the patient is standing or walking, but which action is inhibited or stopped when the patient is anaesthetized and is in a lying position.

The present invention therefore increases both the peak femoral vein flow and pulsatility, leading to the same mean mass transfer of blood as when the body is working normally.

In accordance with the present invention, it has been found that the effectiveness of the pneumatic boots is related closely to the pattern of the pressure cycle to which they are subjected. In particular, it has been found that amongst the critical factors are: the rate at

which pressurizing gas is applied to the pneumatic boots; the maximum which this pressure reaches; the speed with which the pressure is reduced, and the timing between successive pressurization cycles. These characteristics are indicated diagrammatically in FIG. 4. Before these are discussed in any further detail, the operation of the venous flow stimulator will be described in further detail.

In the initial, unenergized, state of the stimulator, the bellows **26** is in its deflated condition, being biased to that position by a compression spring (not shown). The detailed construction and operation of the bellows is as described in our UK patent specification No. **866 758**, and so will not be described in greater detail herein. In this position the magnet **28** is more effective than is magnet **22**, thus biasing the rocker **18** open so that the inlet **16** of conduit **34** is in communication with chamber **14**. The exhaust valve **44** is open, allowing the interior of both boots **38** to vent to atmosphere.

When it is desired to start operation of the apparatus, the gas under pressure is applied to pressure switch **52** and to valve **6** from a suitable source, such as a cylinder of compressed air, nitrogen or oxygen. The use of oxygen might seem surprising, in view of its higher cost but it has been found that oxygen is usually more readily available in hospitals than the other gases and so is more convenient to use despite its higher cost. The possible or preferred use of oxygen means that none of the valves in the apparatus, at least on the high-pressure side thereof, can be lubricated, because oxygen can react explosively with some lubricants under certain conditions. The valves are therefore designed with the use of oxygen in mind.

Closure of pressure switch **52** causes the timer **56** to send out a set pulse to solenoid **58**. This switches over valve **6** to the position in which gas under pressure flows through the pressure regulator **8** and into the interior of chamber **14**. From there, the rocker **18** being open, it passes into injector **36**, is diluted with atmospheric air and passes into the operating volume of the pneumatic boots **38**. As soon as a superatmospheric pressure is generated in conduit **34** this causes the exhaust valve **44** to be switched over so that the conduit is isolated from the atmosphere. By virtue of conduits **34** and **42**, the pressure in the interior of the boots **38** is transmitted to the pressure-relief valve **46** and to the interior of control chamber **24** of device **12**. As this pressure is greater than that needed to overcome the force of the biasing spring, the chamber **24** starts to increase in volume, although gas is bled away from chamber **24** at a rate determined by the setting of needle valve **32**. Under normal conditions of operation, the valve **32** bleeds gas away from chamber **24** at a rate much lower than that at which gas enters the chamber from conduit **42**, so that the bellows **26** are distended at a chosen rate. As the magnet **28** is moved away from rocker **18** by this distention of the bellows, there comes a point when the field of magnet **28** is less effective than that of magnet **22**, and the rocker valve closes. This is arranged to take place when the pressure in the interior of boots **38** has reached a desired maximum. According to the teaching of the present invention, a desired rate of pressurization of the boots is such that the operating pressure therein should increase at the rate of **8** mm of mercury (Hg) per second, and the desired maximum value should be of the order of **50** mm Hg, all the pressures being measured above atmo-

spheric. Thus the boots would take about 6–7 seconds to inflate.

When the rocker 18 has switched over, this causes the pressure in chamber 14 to increase until the arrival of the next reset pulse at solenoid 58, but this pressure is not passed on the pneumatic boots, because of the closure of the rocker valve 18. When the reset pulse does arrive, it switches over valve 6 and enables chamber 14 to be vented to atmosphere

With closure of rocker valve 18, the reduction of pressure in conduit 34 allows valve 44 to open, thus venting to atmosphere the interior of both boots 38. It is envisaged that this venting would take place under the natural compliance of the system but it could be assisted by a partial-vacuum device (not shown) adapted to apply a measure of vacuum to the interior of the boot to increase the rate at which they are deflated. This reduction in pressure closes the non-return valve 48, but the chamber 24 continues to be vented through valve 32, thus allowing magnet 28 to move towards the position in which it is effective to open rocker 28. However, the rate-of-return of magnet 28 is governed so that by the time it is effective to open the rocker valve, the inlet valve 6 has received the reset pulse and closed.

The stimulator then stays in its rest position awaiting the arrival of the next set pulse, which occurs some 100 to 120 seconds after the preceding reset pulse. This interval is usually set by the manufacture of the stimulator, or it may be under the control of the anaesthetist or other person in the operating theatre.

It has been found that the stimulation of the blood-pumping movement of the calf muscles is so effective that the venous flow stimulator of the present invention need be used only during the surgical operation.

It is within the purview of the present invention to apply the pressure pulses to the two boots alternately. This would require a modification in the outlet circuit of the stimulator, involving principally the addition of a pneumatic flip-flop valve, and to altering the timing circuit of the stimulator so that it generates pulses of the same shape but at twice the frequency described above. This would ensure that alternate pulses would be applied to each of the boots, so that each of the boots would receive exactly the same cycle of pulses as described above, but with the two cycles being out of phase with each other. However, so far it has been found by experiments that there is no significant advantage to the patient in having alternate pressurization of the boots, and so the additional cost and complication of providing this option are not usually justified.

What we claim is:

1. An apparatus useable in conjunction with a source or pressurized gas for stimulating venous blood flow in the legs of patients undergoing surgery, said apparatus including at least one double-walled pneumatic boot positioned on and completely enclosing a patient's leg and foot; said boot having an operating space defined between the walls thereof; a supply valve operative to control the supply of gas at a suitable pressure from a pressurized source to the operating space; means responsive to the gas pressure in the operating space for closing the supply valve when the pressure reaches a chosen maximum valve; a timer means adapted to produce a series of successive set and reset pulses, and an inlet valve means, controlled by the timer, for supplying gas to the supply valve upon receipt of a set pulse, and for discontinuing the supply of gas upon receipt of a reset pulse.

2. A venous flow stimulator as claimed in claim 1, including injector means positioned downstream of the supply valve between the supply valve and boot for receiving high-pressure gas from the open supply valve and for diluting it with atmospheric air thereby producing a larger volume of gas at lower pressure for feeding to the pneumatic boot as long as the supply valve is open.

3. A venous flow stimulator as claimed in claim 1, including means for energizing the timer only when the pressure of the supply of gas to the said inlet valve is above a chosen minimum.

4. A venous flow stimulator as claimed in claim 3, in which the timer is electronic and is composed of units of integrated circuitry.

5. A venous flow stimulator as claimed in claim 1, in which the said supply valve includes a magnetic rocker valve and two permanent magnets mounted for relative movement, said rocker valve being operated by relative movement of said magnets.

6. A venous flow stimulator as claimed in claim 5, in which the said supply valve includes a bellows having a portion thereof movable relative to said rocker valve, said movable portion carrying one of the said two permanent magnets for movement thereof toward and away from actuating relationship with the rocker valve.

7. A venous flow stimulator as claimed in claim 6, including an adjustable bleed valve in the bellows, said bleed valve venting the bellows to atmosphere at a desired rate.

8. A venous flow stimulator as claimed in claim 1, including an exhaust valve biased to the open position, said exhaust valve being operatively controlled by the outlet pressure of the gas from the supply valve in a manner whereby when the outlet pressure exceeds a chosen valve the exhaust will close, the inlet of the exhaust valve being in communication with the operating space of the boot for a selective venting thereof.

9. A venous flow stimulator as claimed in claim 4, in which the timer produces set and reset pulses of opposite polarity.

10. A venous flow stimulator as claimed in claim 9, in which the intervals between successive set and reset pulses is approximately 10 seconds, and between successive reset and set pulses is approximately 100 – 120 seconds.

11. A venous flow stimulator as claimed in claim 10, in which shunted across input terminals of the timer is a capacitor adapted to be discharged through the timer to contribute energy to the pulses, and to be charged in the intervals between the pulses.

12. The method of stimulating venous blood flow in the leg of a patient undergoing surgery comprising intermittently forcing blood from the veins of the leg by an intermittent pressurization of a leg and foot encasing pneumatic boot at an increasing rate of 8 mm of mercury per second to a maximum on the order of 50 mm of mercury, and subsequently releasing the pressure.

* * * * *